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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,743	07/03/2001	Krassen Dimitrov	P-IS 4548	3666

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,743	Applicant(s) DIMITROV, KRASSEN	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 16-78, 80-82 and 85-89 is/are pending in the application.
- 4a) Of the above claim(s) 16-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 78, 80-82 and 85-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/23/04</u> | 6) <input type="checkbox"/> Other: _____ |

PD

DETAILED ACTION

1. Applicants' amendment and response to the office action filed on February 24, 2005 has been entered.

Status

2. Claims 1-3, 7-12, 78, 81-82 are amended. New claims 85-89 are added. Claims 13-15, 79, 83-84 are cancelled, and new claims 85-89 are added. Claims 16-77 are withdrawn in view of restriction/ election. Applicants' response to the office action and the amendment are fully considered and found persuasive. All arguments have been fully considered and thoroughly reviewed, and deemed persuasive, in view of the arguments and amendment to delete the limitation "attachment of label monomers of said unique labels to nucleotides in a 1:1 correspondence. This action is made FINAL necessitated by amendment.

New Grounds of rejections necessitated by Amendment

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim interpretation: The instant specification defines gene digit as having any structure including, for example, a single unique sequence or a sequence containing repeated core

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elements, and anti-genedigit as a nucleotide or amino acid or structure that binds specifically to the gene digit, for example if the gene digit is a nucleic acid, the anti-genedigit can be a nucleic acid sequence that is complementary to said nucleic acid sequence (see page 9, line 17-28). Thus in the light of the specification, gene digit is considered as any nucleic acid sequence, and anti-gene digit is considered as a complementary sequence to said nucleic acid sequence, which includes any probe sequence.

A. Claim 1-12, 78, 80-82, 85-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirkin et al. (USPN. 6,361,944).

Mirkin et al. teach claim 1, 86, a diverse population of labels, or unique probes comprising unique labels (each nanoparticle with plurality of oligonucleotide sequences each oligonucleotide having a reporter group) wherein each said unique label comprises at least two anti-gene digits (complementary sequences or oligonucleotide probe sequences) (see col. 22, line 11-23, col. 15, line 50-59, col. 32, line 44-67, col. 33, line 1-65, col. 26, line 56-67, col. 27, line 1-21, indicates one type of nanoparticles having oligonucleotide portions complementary to another type of nonoparticles having oligonulceotide sequences)).

With regard to claim 2, 8, Mirkin et al. teach said unique label comprise about same unit signal (color intensity) or multiple signal intensities (see col. 16, line 64-67, col. 17, line 1-7);

With regard to claim 3, 9, Mirkin et al. teach that said unique labels comprise mixture of two or more different labels (nanoparticles) (see col. 26, line 35-67, col. 22, lines 40-45, col. 29, line 3-60);

With regard to claim 4-5, 10-11, 81, Mirkin et al. teach said unique labels comprise at least two types of labels, (which indicates two or more labels –more can be any number) (see col. 16, line 64-67, col. 17, line 1-7);

With regard to claim 6, 12, 82, Mirkin et al. teach that said labels comprise fluorescent labels (see col. 29, line 3-60);

With regard to claims 7, 87, Mirkin et al. teach a diverse population of unique probes (defined sequences) wherein the specific probes (anti-gene digits) are attached in a 1:1 correspondence to at least two gene digits (see col. 22, line 11-20, col. 26, line 56-67, Fig. 24, col. 15, line 50-59, indicates one type of nanoparticles having oligonucleotide portions complementary to another type of nonoparticles having oligonulceotide sequences);

With regard to claim 78, Mirkin et al. teach a kit comprising a target specific probe bound to at least two genedigits (oligomers) and at least two anti-genedigits (see col. 38, lines 4-23).

With regard to claim 80, Mirkin et al. teach that diverse population further comprises a specifier (universal probe), a dendrimer (see Fig. 25B, col. 15, line 60-65, col. col. 40, lines 52-65, col. 28, lines 55-67);

With regard to claims 81, 85, 88-89, Mirkin et al. teach that the diverse population of labels comprise label monomers (oligonulceotides) and the label monomers are combined at different ratios (see col. 26, line 35-43).

Thus the disclosure of Mirkin et al. meets the limitations in the instant claims.

B. Claim 1, 4, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Krantz et al. (USPN. 6,277,583).

Krantz et al. teach a diverse population of labels of claim 1, comprising a library of unique labels (a library includes plurality of affinity labels), wherein each unique label comprises at least two anti gene digits (complementary sequences) (see col. 6, line 30-57, col. 4, line 3-7, indicates one oligomer monomer portion is complementary to another one of a number of different monomers of the same type (gene digit) and another portion is complementary to the target sequence (gene digit);

With regard to claim 4, unique labels having diversity selected from a group consisting of at least about 100 to 10,000 or more members (see col. 6, line 46-50);

With regard to claim 6, the labels are fluorescent (see col. 9, line 43-50).

Thus the disclosure of Krantz et al. meets the limitations in the instant claims.

Response to arguments:

4. With regard to the rejection under 35 USC 112, second paragraph, Applicants' arguments and the amendment are fully considered and the rejection is withdrawn in view of the amendment.

5. With regard to the rejection under 35 USC 102(b), Applicants' arguments and the amendment are fully considered and the rejection is withdrawn in view of the amendment.

6. With regard to the rejections under 35 USC 102(e), Applicants' arguments are fully considered and found not persuasive. Applicants argue that the amended claims recite anti-gene digits and are not anticipated by the prior art of the record (Mirkin et al. Krantz et al.).

Applicants' arguments and amendment are fully considered and found not persuasive because the instant specification broadly defines gene digits and antigene digits on page 9 of the

specification and thus the broader scope of these terms do not exclude any target and probe sequences as gene digits and anti-genedigits. To address the amended claim limitations the rejections are re-written above.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER
4/24/05